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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,772	06/27/2003	Joanne Fillatti	16518.070	6379

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/606,772	Applicant(s) FILLATTI, JOANNE	
	Examiner Elizabeth F. McElwain	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49,50,52-58,61,62,65,68-72,74,77,78,81,84-88,90-94 and 97-102 is/are pending in the application.
- 4a) Of the above claim(s) 65,68-72,74,77,78,81,84-88 and 90-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49,50,52-58,61,62 and 97-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/12/03;7/8/04;11/16/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed July 28, 2006 has been entered.

Applicant's election with traverse of Group I in the reply filed on July 28, 2006 is acknowledged. The traversal is on the ground(s) that Groups I, V and IX should be examined together since they claim the same plant species and have the same classification. This is not found persuasive because each of Groups I, V and IX are drawn to soybean plants having different phenotypic characteristics, wherein each group would require a different search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 49-50, 52-58, 61-62 and 97-102 are in the elected group and are examined on the merits.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 49-50, 52-58, 61-62 and 97-102 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a soybean plant having a nucleic acid molecule comprising a promoter functional in a host plant cell operably linked to a polynucleotide having the sequence of SEQ ID NO: 2 or a complement thereof and a transcriptional termination region, wherein seed of said soybean plant has a fatty acid composition of about 26-80% oleic acid, about 2.97%-49.92% linoleic acid and about 3.38-8.81% linolenic acid, does not reasonably provide enablement for a soybean plant transformed with said nucleic acid molecule wherein the nucleic acid has as little as 70% identity to SEQ ID

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NO: 2 and any fragment of said nucleic acid or its complement. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

3. The claims are drawn to a soybean plant having a nucleic acid molecule comprising a promoter functional in a host plant cell operably linked to a polynucleotide having a sequence that is at least 70% identical to SEQ ID NO: 2 or a complement thereof or is a fragment of either, and a transcriptional termination region, wherein seed of said soybean plant has a fatty acid composition of about 26-80% oleic acid, about 2.97%-49.92% linoleic acid and about 3.38-8.81% linolenic acid. The specification provides examples of sense and antisense constructs of SEQ ID NO: 2 transformed into soybean plants to produce soybean plants having seeds with the claimed ranges of fatty acid composition. However, the specification does not provide examples of any other sequences or fragments thereof that are encompassed by the claims.

4. In addition, De Luca teaches that modifying plant biosynthetic pathways by transforming plants with nucleic acids associated with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that “on many occasions desired goals have been impossible to achieve” (see the last paragraph on page 228N). Thus, given the unpredictability of identifying which sequences that have as little as 70% identity to SEQ ID NO: 2 or consist of a fragment thereof, which could be as small as one nucleotide will result in production of a transformed soybean plant having seeds with the claimed fatty acid composition; and given the general unpredictability of using a sequence to transform a plant and modify the lipid composition of a plant as taught by De Luca; the lack of guidance in the specification for identifying and using other sequences that are encompassed by

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the claims to produce the claimed soybean plant; and given the lack of working examples to demonstrate that sequences other than SEQ ID NO: 2 will have the same result in modifying soybean fatty acid composition as claimed; and given the breadth of the claims which encompass a multitude of sequences that have as little as 70% identity to SEQ ID NO: 2 and any fragment thereof; it would require undue experimentation by one skilled in the art to make and use the invention.

5. The prior art does not teach or suggest a soybean plant transformed with the soy fad2-1A intron of SEQ ID NO: 2 having a seed fatty acid composition of about 26-80% oleic acid, about 2.97%-49.92% linoleic acid and about 3.38-8.81% linolenic acid.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM